

K132440

Entellus Medical



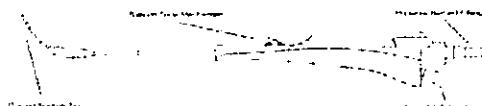
510(k) Summary

OCT 04 2013

Date Prepared: August 5, 2013
Submitter Information: Entellus Medical, Inc.
3600 Holly Lane North, Suite 40
Plymouth, MN 55447
Establishment Registration: 3006345872
Contact Information: Karen E. Peterson
Vice President Clinical, Regulatory and Quality
(763) 463-7066
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Device Information:
Trade Name: XprESS Multi-Sinus Dilation Tool
Common Name: Sinus Balloon Dilation System
Classification Name: ENT Manual Surgical Instrument
Product Code: LRC
Regulation Number: Class I, 21 CFR 874.4420
Predicate Device: XprESS Multi-Sinus Dilation Tool,[K121943]

Device Description:

The XprESS Multi-Sinus Dilation Tool is intended to remodel or recreate the sinus outflow tract via trans-nasal balloon dilation. The XprESS device combines features of a curved suction tip and a frontal ostium seeker with the tissue expansion effect of balloon dilation. The familiar features of this device enable a physician to track the device to the sinus ostium using endoscopic visualization. Since the distal end of the device is re-shapeable, one balloon can be modified to work on multiple sinuses within the same patient.

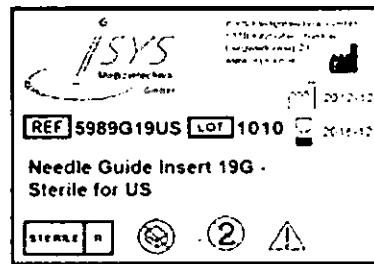
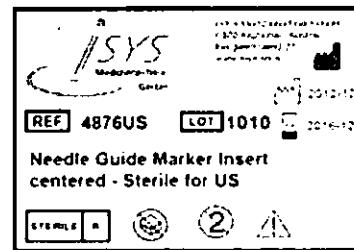
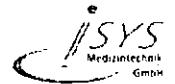


XprESS Multi-Sinus Dilation Tool

The XprESS curved suction tip has an atraumatic ball tip. A suction tube may be connected to the proximal barbed fitting to provide active suction by covering the suction vent. An Extension Line connected to a syringe may be connected to the proximal barbed fitting to provide irrigation. The device was designed to prevent fluid from exiting the suction vent during irrigation.

The XprESS Multi-Sinus Dilation Tool is provided sterile and for single use only.

PD/B18

Proposed Labeling
510(k) Number: K131433

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Created by: Oliver Spitz	Approved by: Dr. Michael Vogele	Invalid since: Source: FO_42_1996



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 4, 2013

Entellus Medical, Inc.
% Karen E. Peterson
Vice President Clinical, Regulatory and Quality
3600 Holly Lane North, Suite 40
Plymouth, MN 55447

Re: K132440

Trade/Device Name: XprESS™ Multi-Sinus Dilation Tool
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, nose, and throat manual surgical instrument
Regulatory Class: Class I
Product Code: LRC
Dated: September 4, 2013
Received: September 5, 2013

Dear Ms. Peterson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Eric A. Mann -S

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

Applicant: Entellus
510(k) Number (if known): K132440
Device Name: XpRESS Multi-Sinus Dilation Tool

Indications for Use

To access and treat the frontal recesses, sphenoid sinus ostia and maxillary ostia/ethmoid infundibula in adults using a trans-nasal approach. The bony sinus outflow tracts are remodeled by balloon displacement of adjacent bone and paranasal sinus structures.

Prescription Use - OR/AND
(Part 21 CFR 801 Subpart D) Over-the-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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